Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of bubble CPAP standard CPAP for treatment of respiratory distress syndrome in premature infants

Protocol summary

Summary

Respiratory distress syndrome is the most common cause of death in premature infants. One of the methods used in the treatment of neonatal respiratory distress syndrome is a continuous positive airway pressure. This is a randomized clinical trial was performed on 40 premature infants. The study population were preterm infants (34-28 weeks gestation) admitted in neonatal intensive care unit of the Shahid Sadoghi hospital. 20 people numbers were calculated for each group of infants was randomly allocated to either the intervention group (Bubble CPAP) or control (standard CPAP). Infants in both groups were followed up for the time required mechanical ventilation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014032716870N2**
Registration date: **2014-04-19, 1393/01/30**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-04-19, 1393/01/30

Registrant information

Name

Khadije Nasiriani

Name of organization / entity

Yazd Shahid Sadoughi University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 35 1824 1755

Email address

nasiriani@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences.

Expected recruitment start date

2012-05-21, 1391/03/01

Expected recruitment end date

2013-12-22, 1392/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of bubble CPAP standard CPAP for treatment of respiratory distress syndrome in premature infants

Public title

Continuous positive airway pressure in premature infants with respiratory distress syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Infants with a gestational age of 28 to 34 weeks with respiratory distress syndrome Exclusion criteria: Life-threatening congenital malformations Severe asphyxia Sepsis hematocrit less than 35 Intracranial hemorrhage and intraventricular hemorrhage grade three or four

Age

To **1 year** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Sadoughi University of Medical Sciences

Street address

Central Buillding of University ,Bahonar Square

City

yazd

Postal code

Approval date

2012-05-07, 1391/02/18

Ethics committee reference number

257428

Health conditions studied

1

Description of health condition studied

respiratory distress syndrome of preterm neonates

ICD-10 code

P22.0

ICD-10 code description

Respiratory distress syndrome of newborn

Primary outcomes

1

Description

Duration of mechanical ventilation

Timepoint

daily

Method of measurement

Registration time day

Secondary outcomes

empty

Intervention groups

1

Description

Group Intervention: The intervention group infants The use of continuous positive airway pressure ventilation Bubble Construction of the New Zealand company Fisher Vpykl The total duration of the study.

Category

Treatment - Devices

2

Description

Control group: The control group infants using: Continuous positive airway pressure ventilation standard Model Bear750psv Made in America During the whole period of study

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi Hospital

Full name of responsible person

Khadijeh Nasiriani

Street address

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Dr.Fatemah Ezoddini

Street address

Deputy for research, Central Building of Shahid Sadoughi University of Medical Sciences, Bahonar Square

City

yazd

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Sadoughi University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Khadijeh Nasiriani

Position

PhD in Nursing

Other areas of specialty/work

Street address

School of Nursing & Midwifery ,Buali st, Safaieh

City

yazd

Postal code

Phone

+98 35 1824 1755

Fax

Email

nasiriani@gmail.com; nasiriani@ssu.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Sadoughi University Of Medical Sciences

Full name of responsible person

Mahmood Noori-Shadkam

Position

Pediatrics/Associate Professor

Other areas of specialty/work

Street address

Shahid Sadoughi Hospital , Reyazi Sq, Safaeye

City

yazd

Postal code

Phone

+98 35 1822 4000

Fax

Email

mahmood_7072005@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Khadijeh Nasiriani

Position

Nursing PhD

Other areas of specialty/work

Street address

School of Nursing Midwifery,Buali street, Safaieh

City

yazd

Postal code

Phone

+98 35 1824 1755

Fax

Email

nasiriani@gmail.com; nasiriani@ssu.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty